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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/535,624	10/25/2005	In-Hee Lee	2393.0010000/JUK/SMW	1731	
26111 7590 02/04/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.			EXAMINER		
1100 NEW YO	1100 NEW YORK AVENUE, N.W.			GUDIBANDE, SATYANARAYAN R	
WASHINGTO	ON, DC 20005		ART UNIT	PAPER NUMBER	
			1654		
			MAIL DATE	DELIVERY MODE	
			02/04/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

*	•					
	Application No.	Applicant(s)				
	10/535,624	LEE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Satyanarayana R. Gudibande	1654				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
_	4 0007					
· — ·:	Responsive to communication(s) filed on <u>16 November 2007</u> .					
.—	·					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	,					
4) Claim(s) <u>1-11</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
• • • • • • • • • • • • • • • • • • • •	Claim(s) <u>1-4 and 11</u> is/are rejected.					
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o	r election requirement					
o/ Claim(s) are subject to restriction and/o	r ciconom roquii omonii.					
Application Papers						
9)☐ The specification is objected to by the Examine						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex						
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:		)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
<ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>						
application from the International-Bureau		od III tillo National Otago				
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary Paper No(s)/Mail D					
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date 1/30/06, 2/15/07.</li> </ul>	5) Notice of Informal F 6) Other:					

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#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of group I (claims 1-4) and election of species SEQ ID NO: 1 in the reply filed on 11/16/07 is acknowledged.

### **Priority**

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 199(e) or 120 as follows:

Application No. PCT/KR02/02195, filed 11/22/2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29,

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2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

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under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

In the present case, the instant application 10/535,624 was filed on 10/25/2005 after a lapse of 35 months and 3 days after a PCT/KR02/02195 filed on 11/22/2002. Hence the priority to the PCT/KR02/02195 is denied. Please see MPEP, Article 22 which states that, "[T]he applicant shall furnish a copy of the international application (unless the communication provided for in Article 20 has already taken place) and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date. Where the national law of the designated State requires the indication of the name of and other prescribed data concerning the inventor but allows that these indications be furnished at a time later than that of the filing of a national application, the applicant shall, unless they were contained in the request, furnish the said indications to the national Office of or acting for the State not later than at the expiration of 30 months from the priority date".

Claims 1-11 are pending.

Claims 5-10 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-4 and 11 are examined on the merit.

A search for the elected species SEQ ID NO: 1 has indicated that it is not free of art and has been used in the art rejection below.

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### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a chemical formula I as follows,

 $W_1X_2B'_3U_4X_5X_6B_7B_8U_9X_{10}B'_{11}C_{12}U_{13}B_{14}U_{15}X_{16}X_{17}U_{18}$ 

W represents tryptophane or its derivatives;

X represents more than one amino acid residue selected from a group consisting of tyrosine, valine, isoleucine, methionine, phenylalanine and tryptophane, and the derivatives thereof;

B represents more than one amino acid residue selected from a group consisting of arginine, lysine and histidine, and the derivatives thereof;

B' represents more than one amino acid residue selected from a group consisting of arginine, lysine and histidine or from a group consisting of asparagine and glutamine, and the derivatives thereof; and

U represents more than one amino acid residue selected from a group consisting of glysine, serine, alanine and threonine, and the derivatives thereof.

However, the elected species, SEQ ID NO: 1 corresponds to the following peptide,

Trp Leu Asn Ala Leu Leu His His Gly Leu Asn Cys Ala Lys Gly Val Leu Ala

Wherein,  $X_2$ ,  $X_5$ ,  $X_6$ ,  $X_{10}$  and  $X_{17}$  = Leu in the elected species. The amino acid Leu does not belong to the Markush group of X variable in the formula I of claim 1. Therefore, the elected species does not read on the compound of formula I of claim 1. Therefore, the

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claims as recited are vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Moreover, the claims as recited and specification as disclosed does not provide proper definition for the term "derivatives thereof" when referring to the amino acids recited in claim 1 such as what modifications are made to amino acids to render them derivatives.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Jang, et al., 2002, FEBS letters, 521, 81-86.

The instant claim 4 is the peptide of SEQ ID NO: 1 which is represented by the amino acid sequence, Trp Leu Asn Ala Leu Leu His His Gly Leu Asn Cys Ala Lys Gly Val Leu Ala.

The reference of Jang, et al., teaches the identical peptide, Trp Leu Asn Ala Leu Leu His His Gly Leu Asn Cys Ala Lys Gly Val Leu Ala (abstract). Therefore, the cited reference of Jang, et al., anticipates the instant invention.

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Please note: Claims 1-3 and 11 have not been rejected over Jang, et al., because, the SEQ ID NO: 1 as recited is not encompassed by the formula I as since Leu does not belong to the Markush group of X variable in the formula I of claim 1. If the claims are amended to include the Leu in the Markush group, the claims are anticipated by the cited reference of Jang, et al.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Śatyanarayana R. Gudibande, Ph.D.

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